

EXAMINER'S AMENDMENT

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization of this Examiner's amendment was given in a telephone interview with Mr. Leonard Svensson on January 8, 2010.
3. The Claims have been amended as follows:

Claim 28 (Currently Amended) A process for obtaining a cryoprecipitable protein[[s]] comprising:

- (a) contacting a composition [[of the]] containing a cryprecipitable protein of interest with a stabilizing and solubilizing formulation comprising a mixture of arginine, at least one hydrophobic amino acid and trisodium citrate; [[and]]
- (b) transforming said protein composition into a freeze-dried protein; and
- (c) performing a virus inactivation step by heat treatment of said freeze-dried protein.

2.(Currently Amended) The process of claim 1, wherein

Art Unit: 1652

[[that]] the formulation consists essentially of the mixture of arginine, the hydrophobic amino acid and the trisodium citrate.

3.(Currently Amended) The process of claim 1, wherein arginine is present in a concentration [[of]] from 25 to 50 g/l.

4. (Currently Amended) The process of claim 3, wherein the concentration of arginine is [[of]] from 35 to 45 g/l.

5.(Currently Amended) The process of claim 1, wherein the trisodium citrate is present in a concentration [[of]] from 0.5 to about 12 g/l.

7. (Currently Amended) The process of claim 6, wherein leucine, iso-leucine or mixture thereof are present in a concentration [[of]] from 5 to 15 g/l.

8. (Currently Amended) The process of claim 6, wherein the concentration of leucine or iso-leucine or mixture thereof is [[of]] from 9 to 11 g/l.

10. (Currently Amended) The process of claim 9, wherein glycine and lysine are each present in a concentration [[of]] from 1 to 5 g/l.

11. (Currently Amended) The process of claim 9, wherein each [[of these]] concentration [[s]] of glycine and lysine is [[of]] from 1.5 to 2.5 g/l.

14. (Currently Amended) The process of claim 1, further comprising, prior to step (a), at least one step of virus inactivation and/or elimination from the said composition of cryoprecipitable protein[[s]] by solvent-detergent and/or by nanofiltration on filters of 35 nm.

17. (Currently Amended) A concentrate comprising a cryoprecipitable protein comprising a stabilizing and solubilizing formulation added to the protein prepared by the process [[according to]] of claim 1.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Conclusion

6. Claims 1-14 and 16-19 are allowable.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652